

quantitating breast cancer protein, classified in class 435, subclass 500.

- Group III. Claims 20 and 21, drawn to a pharmaceutical composition, classified in class 424, subclass 1.49.
- Group IV. Claims 22-24, drawn to a method of treating breast cancer via nucleic acid (antisense) therapy, classified in class 514, subclass 44.
- Group V. Claims 25-27 and 38, drawn to a method of screening for an agent interacting with a breast cancer protein, classified in class 530, subclass 387.1.
- Group VI. Claims 28-30 and 39-41, drawn to an *in vitro* method of modulating the expression of a breast cancer protein, classified in class 436, subclass 512.
- Group VII. Claims 31-37, drawn to an *in vivo* method of modulating the expression of a breast cancer protein, classified in class 424, subclass 130.1.
- Group VIII. Claims 42-44, drawn to a prognostic method of breast cancer on an array, classified in class 435, subclass 6.

Responsive to the Requirement for restriction, Applicants elect to prosecute the invention of Group II, with traverse, Claims 8-19, which are drawn to a method of diagnosing breast cancer via quantitating breast cancer protein.

Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group of claims designated by the Examiner in the present Application, for the reasons provided as follows.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "'independent'" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct'" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct

inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

Applicants respectfully submit that the groups designated by the Examiner fail to define different methods, with properties so distinct as to warrant separate Examination and Search. Claims 1-7 of Group I are drawn to a method of diagnosing breast cancer via 2-D gel analysis that are fundamentally related to Claims 8-19 of Group II, drawn to a method of diagnosing breast cancer via quantitating breast cancer protein. The search for any of the methods separately classified by the Examiner as the invention of Group I would require an additional search of the **identical** classes wherein the claims of Group II are classified, thus resulting in a duplicate search for the same material. It is noteworthy in this regard that 2-D gel electrophoresis, to which the method of Claims 1-7 of Group I is drawn, is one of the methods which may be performed in accordance with the method of Claims 8-19 of Group II. Applicants, therefore, submit that the Search and Examination of the entire Application, or, at least, of Group I with Group II can be made without serious burden, and therefore the Examiner should rejoin the claims of these groups.

Moreover, Applicants assert that Claims 42-44 of Group VIII, which relate to a method of detecting breast cancer by identifying one or more nucleic acid sequences encoding a breast cancer-associated protein isoform of the claims of Group II on an array is not patentably distinct from the invention of Groups I or II. Thus, Applicants submit that the Search and Examination of the entire Application, or, at least, of Groups I and VIII with Group II can be made without serious burden, and therefore the Examiner should examine all of the claims of the Application

on the merits.

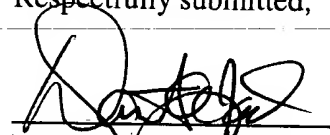
The Examiner's assertions to the contrary notwithstanding, Applicants respectfully submit that conjoint examination and inclusion of all of the claims of the present Application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction, or, at the least, modification to include the claims drawn to Group I, Group II, and Group VIII are in order.

The Examiner has also indicated that should Groups I-III or VIII be elected for further prosecution, Applicants are required to elect a single species. Accordingly, Applicants elect BF-227/BP1-209 (acid ceramidase) for further prosecution.

No fees are believed to be necessitated by the foregoing Response. However, should this be erroneous, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

In view of the above, withdrawal of the Requirement for the Restriction is requested, and an early action on the merits of the claims is courteously solicited.

Respectfully submitted,



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